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REMARKS

The Examiner has rejected claims 21 and 23 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6,656,501. The Examiner has provisionally rejected claim 24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/956,301.

The Examiner has rejected claim 15 under 35 USC 112, second paragraph.

With regard to the Examiner's rejections based on the cited references, the Applicant has briefly summarized these rejections since a significant number of the claims have been cancelled. The rejections pertaining to the remaining independent claims are discussed in detail in the ensuing discussion. The Examiner has rejected claims 1-36 as being unpatentable over the cited references Sherwood et al. U.S. Patent No. 5,725,884, Wong et al. U.S. Patent No. 5,198,229, Eckenhoff U.S. Patent No. 5,098,425, Voss et al. U.S. Patent No. 4,548,825, Berta U.S. Patent No. 4,820,524, Ranade U.S. Patent No. 4,803,076, and Chow et al. U.S. Patent No. 4,959,219.

The Applicant has cancelled claims 1-4, 7, 9-11, 13-17, 19 and 25-36 thereby rendering moot any rejections directed to

these claims.

Applicant has added new claim 37.

The Applicant is submitting herewith a first terminal disclaimer with respect to claims 21-23 and commonly owned U.S. Patent No. 6,656,501, and a second terminal disclaimer with respect to claim 24 and commonly owned application no. 10/956,301.

The Examiner has rejected claims 18 and 21-24 under 35 USC 103(a) as being unpatentable over Eckenhoff U.S. Patent No. 5,098,425. Eckenhoff teaches a method of administering a ruminant dispensing device to ruminant animals. Eckenhoff strictly teaches a dispensing device for ruminant animals. There is no disclosure in Eckenhoff that teaches or suggests that such a dispensing device can be used on humans. Furthermore, the Examiner has acknowledged that Eckenhoff does not expressly teach the weighting of the dispensing device affects the swallowing of the dispensing device. The dispensing device of Eckenhoff includes a density member or weight means (19). The weight means (19) is used for initially retaining dispensing device (10) in the rumen-reticular sac of a ruminant. The weight means (19) allows the dispensing device (10) to remain in the rumen during the dispensing period before the dispensing device (10) passes into the alimentary tract and is

eliminated therefrom. (column 10, lines 1-10). Eckenhoff discloses that the density member or weight means (19) can be iron, iron shot, iron shot coated with iron oxide, iron shot magnesium alloy, steel, stainless steel, copper oxide, a mixture of cobalt oxide and iron powder, a mixture of iron and copper oxide and the like. (column 10, lines 22-27). Eckenhoff discloses eight examples wherein at least one of these metal substances is used as the weight means or density member. Certainly, such metal substances are not suitable for human ingestion. Attached hereto is a true and exact copy of the Declaration of John Cooker Under Rule 132, filed June 27, 2002 in parent application no. 09/614,243, now U.S. Patent No. 6,656,501. In the aforesaid Declaration, paragraph 4, Applicant has stated that such metal substances are not suitable for human ingestion.

On the other hand, the capsule recited in claims 18, 21 and 24 recite that the filler is digestible. Claim 21 specifically recites that the digestible filler is chosen from the group consisting of sucrose, dextrose, lactose, fructose, microcrystalline cellulose, sorbitol, xylitol, isomalt, gelatin, and starch. Such fillers are organic and are clearly suited for ingestion and digestion by humans. As stated in the foregoing discussion, the weight means (19) of Eckenhoff is used for

initially retaining dispensing device (10) in the rumen-reticular sac of a ruminant. In fact, the Eckenhoff patent discloses that it is an "object of the invention to provide a therapeutic dispensing device that can remain in the rumen of a ruminant for a prolonged period of time". (column 2, lines 7-9). The dispensing device of Eckenhoff would not work as intended if the weight means (19) consisted of the digestible filler recited in claims 18, 21 and 24. If a prior art reference is cited that requires some modification in order to meet the claimed invention and such a modification destroys the purpose or function of the invention disclosed in the reference, one of ordinary skill in the art would not have found a reason to make the claimed modification. In re Gordon, 221 USPQ 1125 (Fed. Cir 1984). Thus, there is no technical motivation to make the modifications to the Eckenhoff dispensing device which are necessary to arrive at the claimed capsule. Thus, Applicant submits that the claimed capsule is not rendered obvious by Eckenhoff because:

- 1) Eckenhoff discloses a dispensing device that is strictly for use with animals such as ruminants;
- 2) Eckenhoff does not expressly teach the weighting of its dispensing device affects the swallowing of the device;

- 3) Eckenhoff discloses the use of metals as weight means to keep the dispensing device in the rumen of the ruminant and such metals are not suitable for human ingestion;
- 4) modifying the Eckenhoff dispensing device to use the organic fillers recited in claim 21 instead of the metals disclosed in Eckenhoff would destroy the purpose or function of the Eckenhoff dispensing device; and
- 5) unlike the metals disclosed in Eckenhoff, the organic filler recited claims 18, 21 and 24 is digestible.

Thus, Applicant submits that Eckenhoff does not teach or suggest the capsule of claims 18, 21 and 24. Applicant further submits that in view of these amendments and remarks, claims 18, 21 and 24 are patentable over Eckenhoff.

Applicant has amended dependent claims 5, 6, 8, 12 and 20 to depend from claim 21. Since it has been shown that claim 21 is patentable over Eckenhoff, Applicant submits that dependent claims 5, 6, 8, 12 and 20 are patentable over Eckenhoff.

Applicant has amended claims 22 and 23 to recite a "capsule". Applicant has added new dependent claim 37 that depends from claim 21 and recites that the "first portion of the capsule comprises a cap portion of the capsule and the second portion

comprises a body portion of the capsule". Applicant submits that dependent claims 22, 23 and 37 are patentable over Eckenhoff for the same reasons as mentioned above.

The Examiner has rejected claim 18 under 35 USC 102(b) as being anticipated by Wong et al. U.S. Patent No. 5,198,229. The Examiner has also rejected claim 18 under 35 USC 102(b) as being anticipated by Sherwood et al. U.S. Patent No. 5,725,884.

Applicant has amended claim 18 to recite that the capsule has:

- a) a first portion having an interior;
- b) a second portion ....having an interior;
- c) the active ingredients are within the interior of the first portion;
- d) the digestible filler is within the interior of the second portion; and
- e) the amount and concentration of the filler being such as to eliminate formation of regions within the interior of the capsule that are relatively low density with respect to the liquid with which the capsule is swallowed.

As explained in the copy of the Declaration of John Cooker Under Rule 132 attached hereto, Wong teaches the use of "buoyancy chamber 28 that contains air, gas or other material 40 for providing a low density.....to dispensing device 1.....thus

allowing the device to float in the contents of the stomach (Col. 4, lines 34-39).. The use of such a buoyancy chamber in the capsule of the present invention would significantly increase the buoyancy of the claimed capsule thereby totally defeating the objects of the present invention and the capsule recited in claim 18. The Wong device has no filler added, but achieves density by release of air or buoyant material from itself overtime. The chamber walls, or dense core, of the Wong device do not constitute a filler for a capsule or oral dosage forms, but rather, it is an integral component of this floating device in the Wong device. Therefore, Applicant submits that Wong does not anticipate amended claim 18. Sherwood et al. U.S. Patent No. 5,725,884 was cited by the examiner in parent application no. 09/614,243 (now U.S. Patent No. 6,656,501) but was not relied upon by that examiner to form any rejection. In fact, that examiner in the aforesaid parent application made no statement at all concerning Sherwood. Sherwood is directed to an excipient for use in the manufacture of pharmaceuticals, and in particular, solid dosage forms such as tablets. The objects of the invention of Sherwood are significantly different than the objects of the present invention. Sherwood does not recognize the problems of prior art oral dosage forms which are discussed in the present application, and does not provide any

solution for such problems. Sherwood does not disclose the specific capsule recited in amended claim 18 and therefore, does not anticipate claim 18.

None of the cited references, either taken alone, or in combination, teach or suggest the capsule recited in the claims of the instant application.

Reconsideration and allowance of this application are therefore earnestly solicited.

There is no additional fee due for adding new claim 37.


Applicant is submitting herewith a Petition for Extension of Time for one month and the corresponding fee.

The Examiner is urged to call the undersigned at 203-467-7895 for a telephone conference if the Examiner believes there are outstanding issues regarding this amendment.

Respectfully submitted,

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By:



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